



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/040,707 | 01/07/2002 | Lotfi Chouchane | GCI-0019 | 2203 |
| 7590 | 02/13/2004 | | EXAMINER | |
| Licata & Tyrrell P.C. 66 E. Main Street Marlton, NJ 08053 | | | WILDER, CYNTHIA B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|------------------------------|--------------------------|---------------------|--|
| | 10/040,707 | CHOUCHANE, LOTFI | |
| | Examiner | Art Unit | |
| | Cynthia B. Wilder, Ph.D. | 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 02 July 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-14 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) _____ is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
* a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: ____ .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-5, 13, 14, drawn to a method of identifying an individual at an increased risk of breast cancer, classified in class 435, subclass 6.
 - II. Claims 6-8 and 12, drawn to a method of treating, classified in class 514, subclass 44.
 - III. Claims 9-11, drawn to method of screening to identify compounds, classified in class 435, subclass 7.2

Sequence Election Requirement Applicant to All Groups

In addition, each Group detailed above reads on patentably distinct polymorphisms. Each polymorphism is patentably distinct because the polymorphisms are structurally and functionally unrelated, and a further restriction is applied to each Group. Applicant must further elect a single polymorphism selected from the group consisting of the polymorphism on the TNF- α gene at the -308 locus or the polymorphism on the HSP70-2 gene at the 1267 locus. Applicant must specifically identify the corresponding polymorphisms elected corresponding claims.

Applicant is advised that examination will be restricted to only the elected polymorphism: and should not to be construed as a species election. The non-elected polymorphism and claims depending therefrom will be withdrawn from prosecution.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II and III are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation leading to different effects. For example, the method of Invention I is drawn to a method of identifying an individual at an increased risk of breast carcinoma which operates by a polymerase chain reaction and electrophoresis process to identify a polymorphism associated with a predisposition to cancer, whereas invention II is drawn to a screening assay which operates via a binding assay to identify compounds that stimulate or inhibit the synthesis or action of a polymorphism and finally invention III which is drawn to a method of treating a patient is unrelated to inventions I and II in that the invention of Group III requires administering to a patient an effective amount of an antagonist in a pharmaceutically acceptable carrier to manage or promptly treat patients having a predisposition to breast carcinoma. The different inventions are patentably distinct requiring different fields of search.

3. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

Cynthia Wilder
CYNTHIA WILDER
PATENT EXAMINER
1637 2/9/04